United States Court of Appeals

for the Second Circuit

PETITIONER'S BRIEF

77-4097

To be argued by
MILTON A. BASS

In The

United States Court of Appeals

For The Second Circuit

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION, THE NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS AND SOLGAR CO., INC.,
Petitioners

vs.

DONALD KENNEDY, Commissioner of Food and Drugs, and UNITED STATES DEPARTMENT OF HEALTH EDUCATION & WELFARE, Food and Drug Administration,
Respondents.

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BRIEF FOR PETITIONERS

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SECOND CIRCUIT

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(10127)

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DONALD KENNEDY, Commissioner of Food & Drugs, and UNITED STATES DEPARTMENT OF HEALTH EDUCATION & WELFARE, Food and Drug Administration,

Respondents.

BRIEF FOR PETITIONERS

INTRODUCTION

Petitioners respectfully submit the instant brief in support of their petition for review of administrative orders as set forth herein. The jurisdiction of this Court is based on the judicial review provisions of §701(f) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. §371(f)].

STATEMENT OF ISSUES PRESENTED

1. Whether the dietary supplement regulations should be vacated for failure of the agency to give proper notice and opportunity for comment prior to promulgating them as final rules?

2. Whether the agency improperly promulgated a standard of identity for dietary supplements intended for use by pregnant and lactating women and children under the age of twelve years.

3. Whether the agency erred in retaining minimum potency requirements for dietary supplements.

4. Whether the agency erred in continuing limitations on maximum quantities of components of dietary supplements.

5. Whether the agency's unilateral revision of the nomenclature to be used in describing dietary supplements was improper.

6. Whether the agency erred in failing to modify the dietary supplement regulations to take into account the statutory definition of the term "food for special dietary use".

7. Whether the agency erred in failing to modify the provisions of the dietary supplement regulations relating to the listing of ingredients on the label of dietary supplements.

8. Whether the ageny erred in the conduct of the remand directed by this Court.

9. Whether the agency improperly incorporated food additive restrictions on vitamins and minerals as part of the dietary supplement regulations.

10. Whether the regulatory provisions concerning expiration dating for dietary supplements are invalid.

STATEMENT OF THE CASE

This brief is submitted in support of the joint petition of the National Nutritional Foods Association (NNFA), National Association of Pharmaceutical Manufacturers (NAPM) and Solgar Co., Inc. for review of administrative orders promulgated by the United States Department of Health, Education and Welfare, Food and Drug Administration.[1] These regulations are scheduled to take effect on July 1, 1979.[2]

---

1. These final regulations were promulgated as amendments to 21 C.F.R. §§80.1, 125.1, 125.2 and 125.3. 41 F.R. 46170-46176 (October 19, 1976). The regulations as part of a general agency reorganization and republication, were recodified as 21 C.F.R. §§105.3, 105.60 and 105.85. 42 F.R. 14328-14329, 14331-14334 (March 15, 1977). The regulations were further modified at 42 F.R. 20296 (April 19, 1977). A cross-reference table indicating the corresponding sections of the old and new regulations is set forth at 42 F.R. 20292 (April 19, 1977).

2. See 42 F.R. 35152 (July 8, 1977).

This is the second time that the regulations in question come before this Court. On August 2, 1973, the Food and Drug Administration promulgated as final orders extensive and interrelated regulations governing the manufacture, labeling and composition of foods for special dietary use, as well as dietary supplements (21 C.F.R. §§80.1, 125.1, 125.2 and 125.3: 38 F.R. 20717-20718, 20737-20740, August 2, 1973).[3] Judicial review of those orders was had before this Court[4] and this Court rendered an extensive decision which in part vacated some aspects of the challenged regulations and, further, stayed enforcement of the regulations pending a remand to the Food and Drug Administration for further proceedings in accordance with the opinion of the Court. See *National Nutritional Foods Association v. Food and Drug Administration,* 504 F.2d 761 (2d Cir. 1974). Subsequent to the decision of this Court, the Congress enacted new legislation which significantly modified the agency's authority with respect to these regulations. Pub. L. 94-278 Title V, April 22, 1976, adding a new Section 411 to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §350 (hereinafter sometimes referred to as "new vitamin and mineral legislation").

A. The Philosophy of the Dietary Supplement Regulations As Originally Promulgated by the Food and Drug Administration.

The regulations which were promulgated by the Food and Drug Administration on August 2, 1973 (38 F.R. 20708 *et seq.*) were premised on an agency policy and philosophy of drastically restricting and altering the marketing structure of dietary supplements and foods for special dietary use. The primary focus of the original regulations was to drastically limit both the quantitative and qualitative composition of dietary supplements of vitamins and minerals. This was accomplished by three basic provisions in the regulations. First, the agency adopted the "novel" approach [see *NNFA v. FDA,* 504 F.2d at 767-768 (2d Cir. 1974)] of combining its authority under §401 and §403(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §341 and §343(j)] to adopt a restrictive

3. Relevant statutory references are set forth in the Addendum to Petitioners' Brief.

4. On the prior appeal, 15 separate petitions for review were filed. The instant petitioners represent two of the prior petitioners before this Court. In addition, there is a separate petition of Miles H. Robinson, M.D., Docket No. 77-4104, which currently seeks review of these regulations. The Robinson petition notes that it has been filed *pro se* for the reason that a group of six prior petitioners previously before this Court was unable to raise sufficient funds to employ legal counsel.

standard of identity for vitamin and mineral dietary supplements which (1) specified maximum and minimum potencies for ingredients in dietary supplements and (2) prohibited the inclusion in dietary supplements of anything other than an approved list of vitamins and minerals. The latter would have had the effect of excluding from these types of products various food factors whose necessity in human nutrition has not been established, but with respect to which there has been, and continues to be, widespread public interest. See *e.g.*, 21 C.F.R. §125.2 (b)(5) quoted in full at 504 F.2d 799 n. 68. Finally, the agency rounded out this restrictive regulatory effort by classifying any vitamin and mineral product containing potencies in excess of those permitted by the regulations as "drugs." 21 C.F.R. §125.1(h) quoted at 504 F.2d 761 at 771.

B. The Effect of the Earlier Ruling of This Court.

The comprehensive decision of this Court in *NNFA v. FDA, supra,* in part, required the agency to alter its restrictive philosophy. This Court:

1. Invalidated the restrictive drug classification (504 F.2d at 788-789).

2. Enjoined the agency from preventing the inclusion in dietary supplements of vitamins and minerals whose need in human nutrition had been established, but for which there were no U.S. Recommended Daily Allowances (RDA's) (504 F.2d at 786-787).

3. Struck down the "all or nothing" attitude in terms of permissible combinations in dietary supplements and directed the agency to consider alternate formulations in accordance with specific standards and guidelines laid down by the Court (504 F.2d at 785-786).

4. Directed a remand with respect to the validity behind the concept of the U.S. RDA's for the purpose of permitting appropriate cross-examination as to the exact manner of their development (504 F.2d at 792-799).

5. Analyzed, interpreted and qualified various prohibitions which the agency sought to impose on the making of certain statements on the labels and labeling of dietary supplements (504 F.2d at 799-806). The Court directed that one such prohibition be modified to take into account uncontradicted evidence in the record with respect to the iron requirements of children and women of child-bearing age (504 F.2d at 802).

6. Upheld the basic authority of the agency under the Federal Food, Drug, and Cosmetic Act to limit and restrict combinations and potencies of vitamin and mineral products under the standard of identity provisions of §401 of the statute (21 U.S.C. §341).

The remand proceedings gave the agency an opportunity to reconsider the nature of appropriate action with respect to these regulations in light of the decision of this Court. On May 28, 1975 (40 F.R. 23244, *et seq.*), the agency published in the Federal Register its first proposed implementation of the remand directions of this Court. In terms of potency restrictions on vitamins and minerals, the agency's abandoned any maxima with respect to the sale of *individual* vitamins or minerals.[5] Otherwise, the agency adhered to its basic prior philosophy and made various other proposals in purported compliance with the ruling of this Court. NNFA and NAPM submitted objections to the agency in this regard, pointing out various errors in the proposed implementation of the remand.[6]

C. The New Vitamin and Mineral Legislation.

After the ruling of this Court, the Congress specifically responded to the agency's proposed vitamin regulations. The course of administrative proceedings herein was significantly altered by the enactment of new legislation on April 22, 1976 (Pub. L. 94-278 Title V, §501-502, 90 Stat. 410-413, codified in relevant part at 21 U.S.C. §350 adding a new §411 to the Federal Food, Drug, and Cosmetic Act). The central provisions of the new legislation are contained in §411(a) which provides:

> "(a)(1) Except as provided in paragraph (2)—
>
> (A) the Secretary may not establish, under section 201n, 401, or 403 of this Act, maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;
>
> (B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful;

5. 40 F.R. 23244 *et seq.* (May 28, 1975).

6. Exceptions, Objections and Comments of NNFA and NAPM re Tentative Amendments of Final Orders, dated July 14, 1975.

(C) the Secretary may not limit, under section 201(n), 401, or 403 of this Act, the combination or number of any synthetic or natural —

(i) vitamin,
(ii) mineral, or
(iii) other ingredient of food, within a food to which this section applies.

(2) Paragraph (1) shall not apply in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this subparagraph, the term 'children' means individuals who are under the age of twelve years." [21 U.S.C. §350(a)].

The agency is now specifically prohibited (a) from using the standard of identity and labeling provisions of the statute to establish potency limits on vitamins and minerals within foods for special dietary use, and (b) from limiting the combinations and number of vitamins, minerals or *other ingredients* within such foods for special dietary use.[7] The limitation of the agency's authority was made inapplicable with respect to foods represented for use by children under the age of 12 years or by pregnant and lactating women. The agency was directed to amend any regulations previously promulgated which were inconsistent with the new statute. [§501(b) Pub. L. 94-278] [21 U.S.C. §350 n.)].

On October 19, 1976 the agency published in the Federal Register, new final amendments to the previously promulgated regulations.[8] With this announcement, the agency undertook (without allowing opportunity for public participation as required by statute) to unilaterally modify the instant regulations to comply with the new vitamin and mineral legislation. The fundamental approach in this attempted modification was that the restrictive provisions of the prior standard of identity would be removed only as specifically required by the new statute, but that the entire standard of identity would otherwise remain intact for the minority of dietary supplements intended for children under the age of 12 years, or for

7. This new section also codified this Court's invalidation of the agency's attempt to classify certain vitamin and mineral products as drugs. [§411(a)(1)(B)] [21 U.S.C. §350(a)(1)(B)].

8. 41 F.R. 46156, *et seq.* (October 19, 1976).

pregnant and lactating women. The agency adopted this position even though there was nothing in any portion of the record in these proceedings to justify, on a factual basis, the retention of a standard of identity for this limited group in the absence of the general overall standard which had been invalidated by Congress.

On November 30, 1976, petitioners NNFA, NAPM and Solgar filed an "urgent" application with the agency, pointing out that these parties had serious objections to various aspects of the regulations and that the agency had erred in failing to provide for notice and opportunity for comment in accordance with §701(e) of the Federal Food, Drug, and Cosmetic Act. It was pointed out that the new vitamin and mineral legislation specifically directed and required compliance with appropriate rule-making procedures. The petition asked the agency to withdraw the regulations as "final" orders and to republish them together with an opportunity for public comment as required by law. The petition was made for the purpose of "potentially avoiding recourse to further litigation."[9] Four and one-half months later, on April 19, 1977, the agency denied the NNFA, NAPM and Solgar petition and, in addition, once again, made further unilateral changes in the "final" regulations.[10]

ARGUMENT

I.

THE INSTANT REGULATIONS SHOULD BE VACATED FOR FAILURE OF THE AGENCY TO GIVE PROPER NOTICE AND OPPORTUNITY FOR COMMENT PRIOR TO PROMULGATING THEM AS FINAL RULES.

The principle of requiring due notice prior to the promulgation of new rules and regulations which may adversely affect various parties is firmly embedded in administrative jurisprudence. With respect to the instant case, Congress took the trouble to resolve any doubts by expressly directing the agency to amend regulations inconsistent with the new vitamin and mineral legislation in strict compliance with the requirements of 5 U.S.C. §553:

> "The Secretary of Health, Education, and Welfare shall amend any regulation promulgated under the Federal Food, Drug, and Cosmetic Act which is

9. Petition by NNFA, NAPM and Solgar for withdrawal of final order, dated November 30, 1976, p. 3.

10. 42 F.R. 20293-20296 (April 19, 1977).

> inconsistent with . . . [the new vitamin and mineral legislation] and such amendments shall be promulgated in accordance with section 553 of title 5, United States Code. (Act of April 22, 1976, Pub. L. 94-278, Title V, section 501(b), 90 Stat. 411 (21 U.S.C. 350 note).)"

In the instant case, despite the express congressional direction the agency has chosen to ignore the basic requirement for all rule-making proceedings — *i.e.,* prior notice and opportunity for public participation. The Administrative Procedure Act cited by Congress at 5 U.S.C. §553 is explicit in its requirement for compliance with these traditional administrative procedures:

> "(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include —
>
> (1) a statement of the time, place and nature of public rule making proceedings;
>
> (2) reference to the legal authority under which the rule is proposed; and
>
> (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved."

The agency's error in failing to comply with the very statute cited by Congress is more than a mere procedural technicality — it affects most of the substantive issues raised, in that this Court and the parties have virtually no substantive factual record to refer to as regards these issues. Consequently, the regulations are not supported by substantial evidence and are arbitrary, capricious and not in accordance with law.

In promulgating the regulations on October 19, 1976, in significantly revised and amended form, (41 F.R. 46156-46176 October 19, 1976) the Commissioner nowhere explained or gave any reason for not soliciting public comment prior to promulgating the regulations as final rules. Instead, the Commissioner stated that anyone disagreeing with the proposed implementation of the new vitamin and mineral legislation should "seek relief from the United

States Court of Appeals for the Second Circuit forthwith so that the matter can be settled as quickly as possible."[11] The agency was quickly advised of the obvious procedural error involved. NNFA, NAPM and Solgar, by petition dated November 30, 1976, requested the withdrawal of the regulations as final orders and the granting of an opportunity for the submission of comments in accordance with the statutory requirements. Petitioners pleaded with the agency to grant their petition so as to avoid the necessity for recourse to further litigation.

The agency waited more than four and one-half months before ruling on the "urgent" petition submitted. Finally, on April 19, 1977, the agency published in the Federal Register, a total denial of the petition.[12] Although the agency had contended in the October 19, 1976 announcement that there was no basis for any objection to those regulations as they were then published, the agency itself, in the interim, "reconsidered" the regulations and found that there had been a significant omission which made necessary certain modifications and changes.[13] These changes were once again published without any prior opportunity for comment by the public. The agency offered a *post hoc* explanation for denying the NNFA, NAPM and Solgar petition to the effect that the instant regulations were intended by Congress to be exempt from the traditional administrative due process requirements.[14] As already noted, the reverse is true. Congress expressly directed the agency to comply with the administrative procedure requirements set forth in 5 U.S.C. §553.

The agency's effort to escape the notice and comment provision requirements of the Administrative Procedure Act was based on the exemption set forth at 5 U.S.C. §553(b)(B):

> "Except when notice or hearing is required by statute, this subsection does not apply —
> (A) * * *
> (B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and

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11. 41 F.R. 46170, col. 3 (October 19, 1976).

12. 42 F.R. 20292-20296 (April 19, 1977).

13. 42 F.R. at 20295-20296.

14. 42 F.R. at 20296.

> public procedure thereon are impracticable, unnecessary, or contrary to the public interest."[15]

It is respectfully submitted that the claimed exception pursuant to 5 U.S.C. §553(b)(B) is totally without merit because it was niether impracticable nor unnecessary for the agency to give prior notice with opportunity for submission of comments with respect to the promulgation of the instant regulations. In addition, such opportunity for public comment could hardly have been "contrary to the public interest." Moreover, public notice in the instant case is, in any event, "required by statute" (within the meaning of 5 U.S.C. §553(b)) pursuant to the terms of the Federal Food, Drug, and Cosmetic Act [§701(e)(1) (21 U.S.C. §371(e)(1)].[16]

A. Notice and Prior Opportunity for Comment With Respect to the Instant Regulations Would Not Have Been "Impracticable."[17]

The legislative history of the Administrative Procedure Act shows that the "impracticable" exception in 5 U.S.C. §553(b)(B) was intended to be limited to emergency situations:

> "The exemption of situations of emergency or necessity is not an 'escape clause' in the sense that any agency has discretion to disregard its terms or the facts. A true and supported or supportable finding of necessity or emergency must be made and published. '*Impracticable*' means a situation in which

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15. The agency does not claim, as in fact it could not, that an exemption was available pursuant to 5 U.S.C. §553(b)(A). None of the provisions of that subparagraph are applicable in the instant case.

16. It is clear that at least at the outset, the agency violated the provisions of the Administrative Procedure Act because it did not even attempt to give any explanation for dispensing with the notice and opportunity for prior public comment requirements. The exemption relied on by the agency expressly requires that the agency incorporate a finding and brief statement of reasons for dispensing with notice when the rules are first issued. Here, the original agency announcement contained no such explanation. The belated agency attempt to justify such action is an invalid *post hoc* rationalization which is impermissible. *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962); *NNFA v. FDA, supra*, 504 F.2d at 789

17. When the agency finally ruled on the *NNFA, NAPM* and *Solgar* petition with respect to this procedural error, it took the position: "[A]s discussed below the commissioner specifically concludes in this case that notice and public procedure would be impracticable, unnecessary and contrary to the public interest." (42 F.R. 20294, col. 1 (Apr. 19, 1977).

> the due, timely, and required execution of agency functions would be unavoidably prevented by its undertaking public rule-making proceedings." (Emphasis added). H. Rep. No. 1980, 79th Cong., 2d Sess. 1946, p. 24. See also S. Rep. No. 248, 79th Cong., 2d Sess. 1946.

Although the agency lists "impracticality" as a reason for not giving notice and opportunity for comment with respect to these regulations, there is no explanation at all as to why the giving of notice would have been "impracticable." The new vitamin and mineral legislation was enacted on April 22, 1976 and the agency's response to the regulations was not made until October 19, 1976; more than 6 months later. During such time period, there was ample opportunity for the agency to solicit comment from the public as to what changes were necessary in light of the new legislation. There was no emergency situation present in the instant case. Cf. *Nader v. Sawhill,* 514 F.2d 1064, 1068-1069 (Temp. Emergency Ct. of Appeals, 1975). The regulations themselves are not due to go into effect until July 1, 1979.[18]

It is apparent that the agency has not shown good cause for any finding that it was "impracticable" to give prior notice and opportunity for public comment with respect to these regulations.

B. The Agency Had No Cause to Find That Notice and Opportunity for Comment With Respect to the Instant Regulations Was Unnecessary.

The main thrust of the agency's effort to escape the notice requirements of the Administrative Procedure Act appears to be that such notice was unnecessary within the meaning of 5 U.S.C. §553(b)(B). In denying the NNFA, NAPM and Solgar petition, the agency concluded:

> "In summary, these revisions of the regulations essentially represent FDA's non-discretionary compliance with specific restrictions upon its authority imposed by Congress in the new legislation. None of the revisions raises substantial factual or policy issues for resolution by FDA for which notice and public procedure would have been useful. Congress, in promulgating the new legislation, resolved the relevant factual and policy issues by legislative fiat." 42 F.R. 20295, col. 3.

18. See 42 F.R. 34152 (July 8, 1977).

Once again the agency's determination as to a lack of necessity for prior notice and opportunity for public comment in the instant case ignores the long-established view of the scope of this exception. The legislative history referred to above clearly indicates that this exemption was intended to apply only in situations involving "minor" agency action.[19] This provision has been interpreted with respect to the effect of the regulation in terms of its impact on affected persons. In *Texaco, Inc. v. FPC,* 412 F.2d 740 (3d Cir. 1969), an agency claimed that it was "unnecessary" to give notice of a regulation because there would have been only a small impact on the company challenging the regulations. The Court held:

> "It is clear that the new rule compounding interest cannot properly be labeled 'minor' nor one in which the public is uninterested since the compound rate would affect numerous, jurisdictional, natural gas companies and potentially involve large sums of money." *Id.* at 743.

In the instant case, too, the regulations at issue have been the subject of intense controversy and wide-spread public interest over a period of more than 14 years. The agency's recent unilateral actions include substantial modifications of the regulations in purported compliance with recently enacted restrictions on the agency's authority. In no sense of the word can these regulations be considered "minor" as that term has been understood in this context. See also *National Motor Freight Traffic Assn. v. United States,* 268 F. Supp. 90, 95-96 (D.D.C. 1967); *Kelly v. U.S. Dept. of Interior,* 339 F. Supp. 1095, 1100-1101 (E.D. Cal. 1972); *Detroit Edison Co. v. U.S. Environmental Protection Agency,* 496 F.2d 244, 249 (6th Cir. 1974).

The agency further erred in its approach deeming the amendment and final promulgation as being merely a ministerial act in which the public had no interest. Fundamental errors are involved in the agency's reasoning that since it amended the regulations only to comply with the new vitamin/mineral legislation, each of the proposed revisions was directly mandated by the statute and not subject to any input by the public. It apparently did not occur to the agency that there might be other provisions in the regulations which required amendment as a result of the new legislation. In fact, as will

19. "'Unnecessary' means so far as the public is concerned, as would be the case if a minor or merely technical amendment in which the public is not particularly interested were involved." H. Report, No. 1980, *supra.*

be presented more fully in this brief, *infra,*[20] various other provisions are contrary to the spirit and intent of the recent congressional enactment.

As already noted, a crucial aspect in determining whether prior notice is unnecessary within the meaning of U.S.C. §553(b)(B) is the extent of public interest in the regulations. Even if the agency, prior to October 19, 1976, felt that there would be no opposition to these regulations in their present form, the NNFA, NAPM and Solgar petition certainly was sufficient to apprise the agency that a significant segment of the affected public desired the opportunity to participate in the rule-making proceedings in accordance with the statutory requirements.[21] The petition noted:

> "The Food and Drug Administration is aware of the role played by the above-named parties in connection with the ongoing proposed regulations governing vitamin and mineral products over the course of many years. These parties have prominently participated in administrative proceedings before the agency and were in the forefront of those seeking judicial review of the original agency regulations promulgated on August 2, 1973. Consequently, these parties have a vital stake and interest in the above-captioned proceeding and, as a matter of utmost importance, request that the Commissioner give urgent consideration to this petition."[22]

In the face of this clear cut expression of interest by leading participants in the rule-making proceedings, it is hard to understand why the agency chose to deny public opportunity for submission of comments pursuant to 5 U.S.C. §553(b) and §701(e) of the Federal Food, Drug and Cosmetic Act. Interested parties can hardly be expected to go to the expense of making factual, legal and policy

20. See Points II-VII of this brief. The numerous and substantive issues raised on this petition indicate that the agency seriously miscalculated in its estimate of public interest and need for commenting on the regulations.

21. Petition by NNFA, NAPM and Solgar for withdrawal of final order dated November 30, 1976 at p. 1.

22. A request for public comments invites a broad spectrum of views to contribute to the decision-making process in any rule-making proceeding. Although NNFA, NAPM and Solgar requested the opportunity to submit comments in accordance with statutory requirements, if the agency had complied, there could have been additional benefit of full public participation including other interested parties.

submissions to an agency which is not willing to consider them in accordance with statutory requirements. As one court noted, "we doubt that persons would bother to submit their views or that the secretary would seriously consider their suggestions after the regulations are a *fait accompli*." *Kelly v. U.S. Department of Interior, supra,* 339 F. Supp. at 1101. The very purpose of the notice and comment procedure requirements built into the Administrative Procedure Act and the Federal Food, Drug and Cosmetic Act were frustrated by the agency's refusal to consider public comment prior to promulgating the final regulations.[23]

C. Notice and Opportunity for Comment With Respect to the Instant Regulations Would Not Have Been Contrary to the Public Interest.

The final element of 5 U.S.C. §553(b)(B) is the proviso relating to dispensing with notice when such notice would be "contrary to the public interest." The legislative history of the Administrative Procedure Act indicates that the clause "contrary to the public interest" was not intended to be an independent criteria, but rather an explanation of the criteria which constitute good cause for finding notice "impracticable" or "unnecessary."[24] In any event, in promulgating these regulations, the agency has completely failed to show that notice of proposed rule-making together with an opportunity for the submission of comments would have been "contrary to the public interest." The reverse was and remains true. Public input would have enabled the agency to determine what public objections there were to the regulations, what further changes might be needed in terms of the newly enacted vitamin and mineral regulations, and what additional factual or evidentiary materials would have to be considered as part of the rule-making proceedings.

The only "public interest" concern expressed by the agency in

23. In fact, the agency itself on April 19, 1977 felt compelled to modify a significant portion of the regulations which it had promulgated as "final" on October 19, 1976. These modifications relating to the important question of the proper nomenclature for dietary supplements, was once again promulgated unilaterally by the agency even though the agency had already been advised by way of the NNFA, NAPM and Solgar petition that there was a public interest in having prior opportunity for comment with respect to these regulations. See 42 F.R. 20295 Cols. 1 and 2, 20296 Cols. 2 and 3. The complexity and interrelationship of these regulatory provisions are such as to preclude the suggestion that the agency itself was authorized to unilaterally promulgate these regulations without prior notice and opportunity for public comment.

24. " 'Public interest' supplements the terms 'impracticable' or unnecessary'." H. Report No. 1980, *supra.*

denying the NNFA, NAPM and Solgar petition for permission to submit comments was the suggestion that compliance with the statutory procedures might delay implementation of these regulations. (42 F.R. 20296, col. 1). This argument is completely without merit. The four and one-half month time period during which the agency considered the NNFA, NAPM and Solgar petition would have been ample time for the submission of comments for agency consideration. The effective date of the regulations, consistent with a new uniform effective date for all food regulations, has, in any event, been set by the agency for July 1, 1979. See 42 F.R. 35152 (July 8, 1977). Surely, there was and remains more than ample time for the agency to conduct such further proceedings as is required by statute. In response to a similar argument, the Court held in *Kelly v. United States Department of Interior, supra:*

> "While this notice contains an implicit 'finding' that further delay would have prejudiced the Act's beneficiaries, it mentions no supporting 'reasons.' The Secretary argues that over a year had already elapsed between the time Congress had amended the Act and he had changed his regulations, but neither he nor the notice explains why an additional 30 days was critical." 339 F. Supp. at 1101.

Petitioners can readily understand the agency's desire to dispose of these regulations once and for all. In light of the history of these proceedings, however, "delay" could not properly be a factor in denying petitioners, and the public at large, the right to submit comments and participate in this rule-making proceeding. The public interest was not served by the agency's violation of the statutory administrative due process requirements herein.

D. The Amendment of the Instant Regulations Requires Notice and Opportunity for Public Comment Pursuant to §701(e)(1) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §371).

The statutory references accompanying both the October 19, 1976 and April 19, 1977 announcements in the Federal Register with respect to the amendment of these regulations and their promulgation in final form included §701(e) of the Federal Food, Drug and Cosmetic Act as specific statutory authority for their enactment. See 41 F.R. 46176, col. 3 (October 19, 1976) and 42 F.R. 20296, col. 3 (April 19, 1977). Section 701(e)(1) of the statute [21 U.S.C. §371(e)(1)] provides:

> "Any action for the *Issuance, amendment,* or repeal

> of any regulation under section 401, 403(j), 404(a), 406, 501(b), or 502(d) or (h), of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. *The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing . . .*" (Emphasis added.)

In its ruling denying the petition, the agency advances arguments to the effect that these regulations are not within the scope of §701(e)(1) because Congress directed that amendments of any regulations inconsistent with the new vitamin and mineral legislation be promulgated in accordance with 5 U.S.C. §553. As already noted, the latter section also clearly requires notice and opportunity for public comment in this case. Moreover, in enacting §411 of the statute 21 U.S.C. §350, Congress was aware that the Food and Drug Administration had previously promulgated regulations contrary to the spirit and intent of the new vitamin and mineral legislation. The agency misinterprets the statutory provision referring to 5 U.S.C. §553 as reflecting congressional intent to depart from the provisions and requirements of §701(e) of the statute. The agency's "inference" that the reference to 5 U.S.C. §553 was designed to bypass the requirements of §701(e) is incorrect. It should be noted that the transitional provision quoted earlier requires the agency to amend *any* regulation which is inconsistent with the new statute. That includes all regulations whether or not they were promulgated under §701(e) of the Act. This Court has held that the agency has authority to promulgate regulations under §701(a) of the statute. *See* 21 U.S.C. §371(a) and *National Nutritional Foods Association v. Weinberger*, 512 F.2d 688 (2d Cir. 1975). The reference to 5 U.S.C. §553 was clearly designed to cover the entire spectrum of FDA regulatory authority under whatever section such an inconsistent regulation might have been promulgated.

The agency's error in this respect is apparently based on the premise that the only regulations requiring amendment as a result of the new vitamin and mineral legislation are the instant regulations promulgated under §701(e) of the Act. In fact, other regulations, however, also require such amendment. For example, 21 C.F.R. §101.9(i)(5) [formerly 21 C.F.R. §1.17(i)(5)] includes a restriction on combinations of vitamins and minerals with non-essential food ingredients in direct violation of the new vitamin and mineral legislation (§411(a)(1)(C) [21 U.S.C. §350(a)(1)(C)]. That regulation was promulgated under §701(a) of the Federal Food, Drug and

Cosmetic Act [21 U.S.C. §371(a)] which does not contain any specific procedures for the promulgation of regulations. Accordingly, the congressional reference to 5 U.S.C. §553 was necessary to deal with all inconsistent FDA regulations, leaving the specific procedures to be determined and governed under the applicable statutory provisions.

The statute provides two exceptions to the notice requirement upon which the agency relies herein [5 U.S.C. §553(b)(A) and (B)], but which are expressly made applicable only "Except when notice or hearing is required by statute." Accordingly, 5 U.S.C. §553(b) expressly disposes of the agency's argument that notice and opportunity for comment were not required in the instant case. The agency cannot avail itself of the supposed exemptions in 5 U.S.C. §553(b)(B) because the statute itself expressly makes these exemptions inapplicable when notice or hearing is required by statute.[25] Herein, an applicable statute, §701(e)(1) of the Federal Food, Drug and Cosmetic Act expressly requires opportunity for public comment without any exceptions whatsoever. The failure to comply with §701(e)(1) of the Federal Food, Drug and Cosmetic Act requires the invalidation of these regulations.[26]

E. The Agency's Failure to Comply With Administrative Due Process Renders the Instant Regulations Void.

Once again in these proceedings, the agency has chosen to take a position with respect to a procedural issue affecting the basic integrity of the entire regulatory process.[27] It has been shown that

25. The introductory clause to 5 U.S.C. §553(b)(A) and (B) reads:
"Except when notice or hearing is required by statute."

26. The agency's argument that §701(e)(1) does not apply because these regulations were promulgated under §411 of the Act [21 U.S.C. §350] is clearly in error. Section 411 per se does not provide for the promulgation of regulations. It merely limits the authority of the agency under other sections of the Act., i.e., §401 and §403 which are sections listed and within the scope of §701(e)(1). Similarly, the transitional provision referred to earlier directs the agency to "amend" earlier inconsistent regulations. In the instant case, the attempted "amendments" relate to §401 and §403(j) regulations. By its express terms, §701(e) applies to any amendment of regulations under these sections.

27. See also *NNFA v. FDA*, 504 F.2d 761 at 796-797 (2d Cir. 1974):

> "The Examiner also denied permission to appeal his adverse ruling to the FDA. He later said he was standing by his ruling 'so that we will have a clear-cut issue which can eventually be determined by the courts.' We must gratify his ill-chosen wish." *Id.* at 795.
>
> "*But one must wonder at the brinksmanship that would imperil a*

(Cont'd)

due notice of proposed revisions and amendments of the dietary supplement regulations was required prior to promulgation of these rules in final form. The agency failed to comply with the administrative due process requirements of 5 U.S.C. §553(b) and §701(e) of the Federal Food, Drug and Cosmetic Act.

A regulation, such as the one promulgated in the instant case, which the agency seeks to implement without compliance with respect to procedural requirements, is invalid, void and of no substantive effect. See, *e.g. N.L.R.B. v. Wyman-Gordon Co.*, 394 U.S. 759, 89 S. Ct. 1426, 22 L. Ed 2d 709 (1969) (plurality opinion); *Wagner Electric Corp. v. Vlope,* 466 F.2d 1013 (2d Cir. 1972); *Texaco, Inc. v. Federal Power Commission,* 412 F.2d 740 (3d Cir. 1969); *Hotch v. United States,* 212 F.2d 280, 14 Alaska 594 (9th Cir. 1954); *Kelly v. United States Department of the Interior,* 339 F. Supp. 1095 (E.D. Cal. 1972); *Pharmaceutical Manufacturers Association v. Finch,* 307 F. Supp. 858 (D. Del. 1970); *National Motor Freight Traffic Association, Inc. v. United States,* 268 F. Supp. 90 (D.D.C. 1967) (three judge court), *aff'd per curiam,* 393 U.S. 18, 89 S. Ct. 49, 21 L. Ed. 2d 19 (1968); *Seaboard World Airlines, Inc. v. Gronouski,* 230 F. Supp. 44 (D.D.C. 1964); *City of New York v. Henry L. Diamond,* 379 F. Supp. 503 (1974). This is particularly true when, as in the instant case, the agency was given an opportunity to correct the procedural error which it made. It is respectfully submitted that the instant regulations should therefore be vacated.

II.

THE AGENCY IMPROPERLY PROMULGATED A STANDARD OF IDENTITY FOR DIETARY SUPPLEMENTS INTENDED FOR USE BY PREGNANT AND LACTATING WOMEN AND CHILDREN UNDER THE AGE OF TWELVE YEARS.

In promulgating these regulations in response to the recently enacted vitamins and mineral legislation, the agency has maintained the old standard of identity in the precise overall form in which it appeared in the original regulations. At first glance, a reading of

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hearing which had already lasted for some eighteen months and was to continue for almost five more by what the Examiner himself recognized to be an exclusionary ruling of dubious validity — even to the point of denying permission to appeal to the agency itself." (Emphasis added.) *Id.* at 796-797.

these regulations gives the impression that they are identical with the ones previously promulgated.[28]

Such an approach is both illogical and unfounded. The new standard of identity for pregnant and lactating women and children under the age of twelve years has no support in any portion of the voluminous administrative record compiled in these proceedings. For example, the regulations in their present form prohibit the combination of non-vitamin and mineral food ingredients, such as rutin [21 C.F.R. §105.60(b)(5)], with vitamin and mineral products. By virtue of the new statute, however, the agency is prohibited from making such a restriction applicable to dietary supplements intended for use by adults and children over the age of twelve years [§411(a)(1)(C)]. The agency's current regulations thereby produce a clearly irrational result. A woman who purchases a typical vitamin dietary supplement product with rutin prior to becoming pregnant will, for no apparent reason, be unable to obtain such ingredient in a formula which is designed for her use during pregnancy or lactation.

Moreover, although previously upholding the agency's authority under the standard of identity provisions of the Federal Food and Cosmetic Act, this Court carefully delineated the criteria which the agency must use in promulgating exclusionary standards. See 504 F.2d 785-786. The current record contains no evidence whatsoever with respect to the application of these criteria to a standard of identity limited solely for pregnant and lactating women and children under the age of twelve years. There has been no showing of confusion among these groups as to dietary supplements which would justify a standard of identity in the first place;[29] nor has there been any factual showing that there would be any less confusion in the marketplace by virtue of the present limited standard of identity. The current limited standard is completely different from the original standard of identity, and as such (not having been the subject of the prior hearings) is necessarily not supported by any substantial evidence of record and arbitrary, capricious and not in accordance with law.

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28. The agency attempted to comply with the restrictions on its authority only by inserting a new paragraph in the regulations which exempts the broad class of dietary supplements from the coverage of the restrictive standard identity. [21 C.F.R. §105.85(e), 42 F.R. 14332 (March 15, 1977)].

29. With respect to children under the age of 12, no basis for a finding of confusion can even be suggested. The purchasers of the dietary supplements are most likely to be the same adults for whom non-conforming dietary supplements are permitted.

It is respectfully submitted that the Court should not interpret the recent vitamin and mineral legislation to permit, let alone require, such an irrational and arbitrary result. The legislative history of the recent amendment to the Food, Drug and Cosmetic Act shows that Congress intended the exact opposite of what the agency has done.

The current vitamin and mineral legislation was first passed by the Senate on December 11, 1975, 121 Congressional Record, pp. S. 21852-21866. The Senate version ultimately became law subject to only a few minor amendments after conference with the House.[30] The exemption from the limitations on agency authority with respect to pregnant and lactating women and children under the age of twelve years had its origin in the Senate version. With respect to these provisions, the legislative history clearly indicates:

> "Mr. PROXMIRE. Mr. President, title IV of S. 988 is the co-called vitamin title. Its purpose is to prevent the Food and Drug Administration from regulating safe vitamins and minerals as dangerous drugs.
>
> I rise today to support that provision of the bill and to chronicle the circumstances and legislative history associated with it..." 121 Congressional Record S.21852, December 11, 1975.

In the course of Senator Proxmire's detailed explanation of the legislation which he had authored, he set forth the limitations on the restrictions of the agency's authority:

> " . . . Further, they do not apply to vitamins and minerals represented for use by pregnant or lactating women and children under the age of 12 years.
>
> *"However, this does not mean that the FDA can merely, once again, arbitrarily set limits on vitamin RDA's for pregnant or lactating women or children and proclaim that an otherwise safe vitamin or mineral is a drug because it is 150 percent of the RDA or meets some other arbitrary standard. It is our view that under the recent appellate court decision the FDA would have to have some objective*

30. H. Conf. Rep. No. 94-1005, 94th Cong. 2d Session, 1976 at p. 25.

standard on which to base its limitations of vitamins or minerals for use by these groups. . . ." (Emphasis added.) 121 Congressional Record S.21856, December 11, 1975.

The legislative history is therefore expressly contrary to the position taken by the agency. The Congress did not intend the exclusions of §411(a)(2) U.S. Code §350(a)(2) to warrant automatic continuation of a separate standard of identity for pregnant, lactating women or children under the age of twelve years. In fact, the Congress understood the prior decision of this Court which was referred to by Senator Proxmire as being sufficient to prevent such an arbitrary result.

Petitioners wish to emphasize that they recognize the potential need for protecting pregnant and lactating women and children under the age of twelve years from possible adverse effects from dietary supplements which might not otherwise be present in the case of adults. Petitioners must object, however, to the agency's arbitrary imposition of potency and combination restrictions for these groups without any factual support or evidence in the record to justify such restrictions in light of the new circumstances whereby the very same restrictions have been eliminated with respect to all other categories of other dietary supplements. No more confusion is incident to use by these groups than is incident to use by the general population nor has there been any showing of safety considerations to warrant such drastic action.

It is respectfully submitted that the standard of identity for pregnant and lactating women and children under the age of twelve years is contrary to the intent of Congress unsupported by substantial evidence of record and, therefore, arbitrary, capricious and not in accordance with law.

III.

THE AGENCY ERRED IN RETAINING MINIMUM POTENCY REQUIREMENTS FOR DIETARY SUPPLEMENTS.

In addition to retaining the restrictive overall standard of identity for pregnant and lactating women, the agency has continued the prior restrictions on *minimum* potencies for vitamins and minerals in *all* dietary supplements.[31]

31. See §105.85(e)(4) as recodified at 42 F.R. 14332 (March 15, 1977).

> "The Commissioner believes that it would be misleading and contrary to the public interest for a vitamin and or mineral preparation represented as a dietary supplement to provide a vitamin or mineral in an amount insignificant for use as a dietary supplement, and Congress, in passing the 1976 vitamin and mineral amendments to the act specifically agreed: 'This provision (21 U.S.C. 350(a)(1)(A)) would not restrict the Secretary (FDA) from prescribing minimum potency levels for vitamins or minerals in such products in order to prevent the addition of insignificant or useless amounts.' (H.R. Rep. No. 94-1005, 94th Cong., 2d Sess. 26 (1976).) The Commissioner has concluded that, for those vitamins and minerals for which U.S. RDA's have been established, dietary supplements should provide, in the specified daily quantity, no less than the lower limit specified in §80.1(d)(1)." 41 F.R. 46166 (October 19, 1976)).

This agency rationale is significantly different from the one provided by the agency upon promulgating these regulations in 1973. The standard of identity provisions generally contain minimum potency requirements for adults and children *four* or more years of age which are generally equal to 50 percent of the U.S. RDA's for these products. For example, the U.S. RDA's for Vitamin A is 5000 IU and the lower limit set by the agency for this category is 2500 IU. The agency's support for establishing quantitative limits was previously based on a finding of fact to the effect that "the establishment of qualitative and quantitative limits on the composition of dietary supplements will reduce consumer confusion concerning choice of dietary supplements by ensuring a basically rational formula for all products" 38 F.R. 20735 (August 2, 1973), Finding of Fact No. 22. See also 38 F.R. 2155 (January 1, 1973). Consumer confusion as to the multiplicty of dietary supplements was therefore the basis for establishing the minimum (along with the maximum) potency requirements.

In light of the fact that the new vitamin and mineral legislation has eliminated most of the provisions in the original standard of identity concerning quantitative and qualitative restrictions, the original basis for prescribing minimum potencies is clearly no longer applicable. The statute now sanctions a multiplicity of dietary supplements in multiple potency ranges and the establishment of a minimum potency level for dietary supplements clearly can not

reduce consumer "confusion" as among the numerous dietary supplements available in the marketplace. There is certainly no evidence in the record to support the retention of minimum potency requirements in light of the elimination of the maximum potency limits. These two factors were considered as one integral regulatory effort and did not receive separate consideration.

As indicated, above, the agency itself has apparently recognized that its rationale for imposing minimum potencies can no longer be grounded on consumer confusion as to choices among the multiplicity of available dietary supplements. Instead, the agency now supports its retention on the grounds that the new statute does not prohibit the imposition of minimum potency requirements and that these requirements are justified to prevent the inclusion of dietary supplements of "insignificant or useless" amounts of vitamins or minerals. The agency cites the legislative history to the effect that Congress intended that the agency retain the authority to "prevent the addition of insignificant or useless amounts." H.R. Rep. No. 1005, 94th Cong., 2d Sess., p. 26, (1976) cited by the Commissioner at 41 F.R. 46166, col. 3, (October 19, 1976).

The retention of authority, however, is not a license to exercise that authority in an arbitrary and irrational manner. The regulations now permit (as they must) the inclusion in dietary supplements of non-vitamin and mineral ingredients which the agency considers to be totally worthless and of no known significance in human nutrition. In this context, how can the agency justify exclusion from all dietary supplements of recognized vitamins and minerals of a given potency which it now considers to be "insignificant" or "useless"? Surely, such a quantity of a vitamin or mineral is at least as appropriate for inclusion as the now permitted substances which the agency had previously sought to totally exclude![32]

Petitioners agree that the intent of Congress was to permit the agency to retain authority to require minimum potencies, but only if consistent with proper evidentiary bases justifying the levels sought to be established as minimums. The agency has completely overlooked, that the minimum levels imposed by these regulations (generally 50 percent of the U.S. RDA's) have not been shown in the record by substantial evidence or otherwise to be the levels at which a quantity of a vitamin becomes "significant." For example, there is no evidence in the record that 40 percent of the U.S. RDA's would be an "insignificant" or "useless" amount of any vitamin or mineral.

32. See *NNFA v. FDA, supra,* 504 F.2d at 787, n. 31, invalidating similarly inconsistent provisions of the earlier regulations.

The agency's position that anything less than 50 percent of the U.S. RDA's is "insignificant" or "useless" is completely unfounded and has no support in these proceedings. In fact, the agency's *post hoc* choice of 50 percent of the U.S. RDA's as a level of "significance" and "usefulness" is contrary to the agency's own regulations which establish a different level of significance in human nutrition for potency levels of vitamins and minerals. The agency's own separate regulations provide:

> "No claim may be made that a food is a significant source of a nutrient unless that nutrient is present in the food at a level equal to or in excess of 10 percent of the U.S. RDA in a serving (portion)." 21 C.R.F. §101.9(c)(7)(v) as recodified at 42 F.R. 14313 col. 2 (March 15, 1977), formerly 21 C.F.R. §1.17(c)(7)(v).

Ten percent of the U.S. RDA is thus considered by the agency itself to be a significant level in human nutrition with respect to a food source for all nutrients.[33] Regulations under §701(e) of the Act are required to be based on substantial evidence of record in proceedings before the agency. See §701(f) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §371(f). Here, the agency has changed the thrust of its rationale for insisting on minimum potency requirements to reflect a new emphasis that dietary supplements contain potency levels which are not "insignificant" or "useless". No corresponding effort was made by the agency to conform to its own regulations as to the appropriate percentages of the U.S. RDA's which are to be considered significant in human nutrition for given vitamins or minerals. It is therefore respectfully submitted that the rationale for maintaining minimum potencies is invalid and that this provision of the regulations is arbitrary, capricious and not in accordance with law.

IV.

THE AGENCY ERRED IN CONTINUING LIMITATIONS ON THE MAXIMUM QUANTITIES OF COMPONENTS OF DIETARY SUPPLEMENTS.

The regulations in their latest form include a restrictive provision on the inclusion of the ingredients in dietary supplements for various purposes:

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33. The agency cannot justify the arbitrary selection of a 50 percent significance level for dietary supplements while at the same time maintaining a ten percent significance level in 21 C.F.R. §101.9(c)(7)(v). See text accompanying n. 32, *supra*.

> "Any safe and suitable substance may be used as preservative, stabilizer, flavor, sweetener, color, seasoning, carrier, base or vehicle, or to facilitate preparation of vitamin or mineral substances. *A dietary supplement shall be prepared so that any such substance contained therein does not exceed the amount reasonably required to accomplish its intended physical or technical effect. . . .* " (Emphasis added.) 21 C.F.R. §105.85(g)(2) as recodified at 42 F.R. 14333 (March 5, 1977).

These provisions are carried over verbatim from the regulations as promulgated on August 2, 1973 (38 F.R. 20739, August 2, 1973). Throughout these lengthy proceedings, there has never been an explanation in any form by the agency explaining the limitation on the quantity of any substances used as a stabilizer, sweetener, base or vehicles, etc. The provisions relating to these types of technical components are based on the agency's Finding of Fact No. 27:

> "It is pharmacologically necessary to allow, in a standard of identity for dietary supplements, for the inclusion of preservatives, stabilizers, colors, sweeteners, seasoning, carriers, bases, vehicles, and other substances which facilitate preparation of the product. However, no greater quantity of any such substances should be allowed to be included than is necessary to establish the desired physical or technical effect." 38 F.R. 20736, col.1 (August 2, 1973).

The apparent explanation for the agency's restriction of the quantity of these substances was that although the standard of identity excluded *any* non-vitamin or mineral ingredients from dietary supplements, the pharmacological necessity of including such items as stabilizers, sweeteners, bases and vehicles warranted an exception permitting their inclusion. Since the inclusion of these substances was permitted only because of pharmacological necessity, the agency apparently felt justified in limiting the quantity of such substances to that which is necessary for such pharmacological purposes. As such, this restrictive provision was incident to the standard of identity provided for by the regulations and perhaps justified under the agency's statutory authority as it existed on August 2, 1973.

The agency's mechanical approach in modifying these regulations after the enactment of the vitamin and mineral

legislation without reconsidering the interrelationships of the various complex provisions involved, once again manifests clear error in this case. Under the current regulations, the majority of dietary supplements may now include any and all safe non-vitamin and mineral food ingredients pursuant to the express language of the statute [§411(a)(1)(C)] [21 U.S.C. §350 (a)(1)(C)]. The agency is now prohibited from limiting the inclusion of other food ingredients in general dietary supplements. The rationale underlying the limitation of the quantity of stabilizers, sweeteners, bases and vehicles has therefore been removed. There is no basis for limiting a safe quantity of these substances when all other substances may be freely included in dietary supplements in any safe quantity.

It should also be noted that the agency's original exclusion of non-vitamin and mineral food ingredients was aimed at such substances as rutin and bioflavonoids. See 21 C.F.R. §105.60(b)(5) as recodified at 42 F.R. 14329 (March 15, 1977). These very substances may have uses as stabilizers, sweeteners, bases or vehicles. The regulations, as currently written, would leave the door wide open for the agency to interpret the restrictive provisions on technical components as being applicable to the very ingredients whose inclusion the Congress intended to permit by way of the enactment of §411(a)(1)(C). The result would be to place a restriction on the quantity of any substance which could be regarded as a preservative, stabilizer, sweetener, base or vehicle without any factual justification. Moreover, since any non-vitamin or mineral ingredient in a dietary supplement might be regarded as a "base" the inclusion of any ingredient other than vitamins and minerals (not needed for pharmacological reasons) could be regarded by the agency as an excess of "the amount reasonably required" to serve as a "base". This provision might be used by the agency to prohibit or limit the inclusion of non-vitamin and mineral food ingredients in dietary supplements in direct contravention of the statutory limitation in §411(a)(1)(C).

This restriction on the quantity of various ingredients in dietary supplements is, on the face of these regulations, in their final form, unsupported by any factual evidence in the record, and arbitrary, capricious and not in accordance with law.

V.

THE AGENCY'S UNILATERAL REVISION OF THE NOMENCLATURE TO BE USED IN DESCRIBING DIETARY SUPPLEMENTS WAS IMPROPER.

One of the central aspects of the original standard of identity provisions was a new nomenclature which the agency developed for the purpose of describing the standardized vitamin and mineral dietary supplements. Based on the hearing record, the agency chose the terms "multi-vitamin" and "multi-mineral" supplements as the common or usual name to be used for vitamins and mineral preparations containing more than one vitamin or mineral in accordance with the standard of identity requirements.[34]

Under the old standard of identity, dietary supplements could consist of either a single vitamin or mineral,[35] or the full spectrum of vitamins and/or minerals required by the standard of identity.[36] Other combinations were excluded and prohibited. On the prior appeal, this Court upheld the agency's general authority to prohibit nonconforming combinations, and in that context only, sanctioned the agency's restrictions on the use of the term "multi-vitamin" supplement for nonconforming products. *NNFA v. FDA, supra,* 504 F. 2d at 785, n. 29.

In first promulgating the instant "final" regulations on October 19, 1976, the agency completely overlooked the fact that the new vitamin and mineral legislation required adjustments with respect to the nomenclature provisions for dietary supplements. The nomenclature provisions continued the old restrictive name designations as were promulgated on August 2, 1973.[37] As such, they were clearly unworkable and unsound, given the entirely revised structure of permissible dietary supplements pursuant to the new statute.

On April 19, 1977, the agency, apparently realizing its error in this respect, unilaterally amended its own prior "final" regulation by providing that vitamin and mineral supplements which did not conform to the prior standard of identity could be designated by "an appropriately descriptive term" [21 C.F.R. §105.85(h)(2)(vii). 42 F.R. 20295, 20296]. The agency also added for the first time and without prior notice and opportunity for comment a provision:

> "That the term 'multivitamin' shall not be used to describe a product that fails to provide all the

34. See former §80.1(h)(2) set forth in *NNFA v. FDA, supra,* 504 F.2d at 770.

35. §80.1(b)(2), 504 F.2d at 769.

36. §80.1(b)(1), 504 F.2d at 768.

37. Compare the old §80.1(h)(2) (quoted at 504 F.2d 770), with the then "Final" §80.1(h)(2) as promulgated at 41 F.R. 46173 (Oct. 19, 1973).

> vitamins identified as 'mandatory', for the group(s) for which the supplement is offered, in the table in paragraph (d)(1) of this section, except as provided in the second proviso clause of paragraph (b)(1) of this section with respect to a liquid multivitamin preparation that does not include folic acid: *And provided further,* That the term 'multimineral' shall not be used to describe a product that fails to provide all the minerals identified as 'mandatory' for the group(s) for which the supplement is offered, in the table in paragraph (d)(1) of this section." 21 C.F.R. §105.85(h)(2)(vii). *Id.*

Aside from the procedural error of promulgating an amendment to these regulations without opportunity for prior notice and comment in accordance with 5 U.S.C. §553(b) and §701(e) of the Federal, Food, Drug and Cosmetic Act [21 U.S.C. §371(e)], the agency seriously erred in prohibiting the use of the term "multi-vitamin" supplement for dietary supplements which are not as comprehensive as the original standard of identity. The agency's mechanical reliance on this Court's prior sanction of such an exclusion is misplaced in light of the new circumstances in which dietary supplements will continue to be available in combinations other than those listed in the regulations. By definition, these could quite properly be designated as "*multi*-vitamin products or "*multi*-mineral" supplements if the manufacturer chose to use such a designation.

The agency's contention is that use of the term "multi-vitamins," or "multi-minerals" for dietary supplements containing less than the full spectrum of vitamins or minerals would cause confusion or be misleading. (See 42 F.R. 20295 Col. 2, April 19, 1977.) This is belied by the very regulations themselves. Folic acid is one of the vitamins which the agency considers to be "mandatory" for inclusion in general full-spectrum dietary supplements. Yet, the regulations state:

> "That folic acid is optional for liquid dietary supplements because of instability of the vitamin in liquid preparations. A liquid dietary supplement *represented as a 'multi-vitamin'* preparation but not containing folic acid shall bear the following statement on the label: 'This product does not contain the essential vitamin folic acid' which shall immediately follow the listing of vitamins and minerals as prescribed in paragraph (i) of this

'section' ". 21 C.F.R. §105.85(b)(1)(v), 42 F.R. 1433 (March 15, 1977)

The agency has thereby recognized that the absence of folic acid does not necessarily preclude the use of the term "multi-vitamin" supplement if a manufacturer discloses the absence of this essential vitamin in the manner described in the regulations. On the other hand, if a manufacturer does not use the term "multi-vitamin supplement" no disclosure is required.

The blanket prohibition on the use of the term "multi-vitamin" supplement without an appropriate option similar to that available in the case of folic acid, is unsupported by substantial evidence and is arbitrary, capricious and not in accordance with the law.

VI.

THE AGENCY ERRED IN FAILING TO MODIFY THE DIETARY SUPPLEMENT REGULATIONS TO TAKE INTO ACCOUNT THE STATUTORY DEFINITION OF THE TERM "FOOD FOR SPECIAL DIETARY USE."

The new vitamin and mineral legislation contains a specific definition of the term "food for special dietary use" as it relates to the subject matter of that section and the provisions of §403(j) of the statute. The new statutory definition provides:

> "For purposes of paragraph (1) and of section 403(j) of this Act insofar as that section is applicable to food to which this section applies, the term 'special dietary use' as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:
>
> (A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.
>
> (B) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

The effect of this definition was to reverse the agency's attempted modification of the term "food for special dietary use" as it had been understood ever since the enactment of the Federal Food, Drug, and Cosmetic Act, and to clarify the scope of the products which are covered by that definition. The statutory definition departs from the agency's prior attempted definition in two significant respects. First, the statutory definition recognizes that a "food for special dietary use" can consist of a vitamin, mineral or "*other ingredient*" where the use is to supplement the diet by increasing total dietary intake. §411(c)(3)(B) [21 U.S.C. §350(c)(3)(B)]. Any ingredient, irrespective of whether it is a vitamin mineral or "other ingredient" and irrespective of whether or not it has a "recognized" utility in human nutrition, is therefore expressly considered a "food for special dietary use" in terms of its function in "increasing the total dietary intake." See §§411(c)(3)(B). In addition, the statutory definition of "food for special dietary use" restores the condition of "disease" as a condition justifying special dietary needs for which "foods for special dietary use" could be used. See §411(c)(3)(A). As will be noted below, both of these aspects of the new definition are very significant in the context of these regulations.

In deference to the statutory definition, the FDA agreed to modify its own definition within the regulations. 41 F.R. 46169, col. 2 (Oct. 19, 1976). Petitioners agree that adoption of the definition of "food for special dietary use" as contained in the statute, was appropriate and required for the regulation which governs the very foods covered by the new vitamin and mineral legislation. The Commissioner, however, failed to analyze the differences between the new and old definition and erred in not making corresponding modifications as required by the new and broader conception of the term "foods for special dietary use."

A. The Regulations Improperly Prohibit "Dietary" Claims for Non Vitamin and Mineral Food Ingredients.

The first sentence of 21 C.F.R. §105.60(b)(5) as recodifed at 42 F.R. 14329, col. 2 (March 15, 1977) continues to provide a prohibition on any representations "that the food has *dietary* properties when such properties are of no significant value or need in human nutrition." (emphasis added). Similarly, with respect to products consisting solely of non vitamin and mineral food ingredients, the regulation continues to require in the third sentence of this subparagraph "that the possibility of nutritional, *dietary,* or therapeutic value" should not be stated or implied.

This restriction on representations of a "dietary" role for non vitamin and mineral food ingredients is directly contrary to the new statutory definition of "foods for special dietary use" and is also contrary to the agency's own regulations which have adopted the very same definition. 21 C.F.R. §105.3(a)(ii) as recodified at 42 F.R. 14328 (March 15, 1977). The statute now expressly recognizes that such "other" ingredients in tablet, capsule or liquid form are considered "foods for special *dietary* use." Since the statute considers these items to be "foods for special *dietary* use," the agency can hardly prohibit representation that the product had *dietary* properties.

The dietary properties which are recognized by the statute and by the agency's own definition is that of serving as a supplement to the human diet by increasing total *dietary* intake. There is no basis in the statute or in the record of these proceedings for prohibiting such representations. The tablets or capsules consisting of or including ingredients whose usefulness is not yet recognized in human nutrition, are sold for those persons who desire these products in accordance with the now sanctioned statutory authority permitting their sale in response to varying nutritional philosophies. They are in fact "useful" for the purpose of increasing the total dietary intake of such products for persons who want such increased dietary intake, and it is factually incorrect and unsupportable to prohibit representations that such products have this "dietary" property.[38]

It is respectfully submitted that the agency's prohibitions with respect to "dietary" properties in the first and third sentences [21 C.F.R. §105.60(b)(5)] are unsupported by substantial evidence of record and are arbitrary, capricious and not in accordance with law.

B. The Agency Has Improperly Retained the Prohibition Against Any Representations that a Vitamin or Mineral Is Effective in the *Prevention* of Disease.

As part of broad prohibitions against various statements in the labeling of foods for dietary use, the regulations in their final form continue to provide that no representations may be made that a food for special dietary use, because of the presence of vitamins or

38. The agency's retention of the prohibition against representations concerning "dietary" properties appears to be a misconception that "dietary" properties are the equivalent of recognized "nutritional" properties. The new statutory definition makes it clear that this approach is unsupportable by including "other ingredients" as part of the concept for "foods for special *dietary* use."

minerals is effective in the "prevention" of disease. 21 C.F.R. §105.60(b)(1) as recodified at 42 F.R. 14329, Column 2, (March 15, 1977).

It is respectfully submitted that in light of the new vitamin and mineral legislation, the agency was required to reconsider this provision or at the very least omit the prohibition as regards the prevention of disease. The new statutory definition of foods for special dietary use was specifically designed to overcome the agency's argument with respect to the role of these foods in "preventing" disease. The agency's original regulations had omitted the "prevention" of disease as a functional aspect of the definition for "foods for special dietary use." In response to the objections to this omission (and the corresponding prohibition concerning the utility of nutrients in the prevention of disease) the agency stated that "disease" factors would render the product a "drug." See 38 F.R. 20708, August 2, 1973, paragraph 2 and 38 F.R. 20710, Column 3, paragraph 14, August 2, 1973:

> "The hearing record establishes and the Commissioner recognizes that all vitamins and minerals inherently assist in preventing nutrient deficiencies and thus, in that sense, prevent disease. The prohibition in no way prohibits truthful representation that a given nutrient is essential to human nutrition and good health and well-being. At the same time it must be recognized that explicit claims related to prevention or treatment of specific disease conditions render a product a drug under section 201(g)(1)(B) of the act." 38 F.R. 20710.

The drug classification rationale relied on in both cases by the Commissioner has since been invalidated by the new vitamin and mineral legislation. As already noted, the new statute expressly includes "disease" as one of the factors by which a food may have utility as a "*food* for special dietary use." See §411(c)(3)(A) [21 U.S.C. §350(c)(3)(A)].

The additional rationale expressed by the Commissioner for this prohibition against disseminating truthful information to the public was based upon evidence in the record of past "scare promotional claims with respect to the onset of deficiency diseases." This Court in upholding the regulations emphasized this aspect and found that the agency had the authority to prohibit statements which where literally true for the purpose of preventing scare promotions. *NNFA v. FDA, supra*, 504 F. 2d at 800 n. 70.

It is respectfully submitted, however, that this aspect too required reconsideration and modification by the agency. At the time of this Court's ruling in 1974, the nature of the first amendment rights as they relate to commercial advertising had not yet been delineated by the Supreme Court of the United States. At that time it was commonly believed that there were no first amendment rights incident to the exercise of commercial speech. This view was predicated upon the often-cited case of *Valentine v. Chrestensen,* 316 U.S. 52 (1942).

It should be noted that the prohibition against references in labeling for foods for special dietary use as to their utility in the prevention of disease is absolute and unconditional and goes far beyond regulating merely scare promotions. The regulation prohibits any and all references to the utility of vitamins and minerals in the prevention of disease irrespective of the context.

Petitioners do not believe that this over-broad approach is consistent with the First Amendment, free speech rights as they have been articulated by the Supreme Court since the prior ruling of this Court with respect to these regulations. See, *Bates v. State Bar of Arizona,* ____U.S. ____ (Docket #76-316, June 27, 1977,) 45 U.S.L.W. 4895-4910; *Lynnmark Associates* with *Willingboro,* ____ U.S. ____, 52 L. Ed. 2d 155 (1977); *Virginia Pharmacy Board v. Consumer Counsel,* 425 U.S. 748 (1976); *Bigelow v. Virginia,* 421 U.S. 809 (1975).

Thus, in *Bates v. Arizona, supra,* the Court sanctioned "restrained" promotional advertising by attorneys and struck down prohibitions against *all* such advertisements. The Court was careful to emphasize that the nature of the advertising determined the scope of a state's authority to infringe upon the First Amendment commercial speech rights involving the flow of useful information to the public. The fact that there was potential for abuse in some forms of advertising by attorneys was not sufficient basis to ban all such advertisements. Similarly, in the instant case, the fact that some forms of advertisements making reference to vitamins, minerals and their prevention of disease, might be misleading and constitute scare tactics, is not a sufficient basis under the standards adopted by the Supreme Court to authorize the banning of all references to the prevention of disease in connection with the labeling and promotion of foods for special dietary use and dietary supplements.

It is respectfully submitted that the agency's blanket prohibition on communicating information with respect to the prevention of disease as regards vitamin and minerals, should be invalidated, and that the agency be directed to re-evaluate and reconsider this

prohibition in light of the constitutional standards as they have emerged in this area in the law.

VII.

THE AGENCY ERRED IN FAILING TO MODIFY THE PROVISIONS OF THE DIETARY SUPPLEMENT REGULATIONS RELATING TO THE LISTING OF INGREDIENTS ON THE LABEL OF DIETARY SUPPLEMENTS.

The dietary supplement regulations in their final form carry over earlier provisions for the listing of ingredients on the label of dietary supplements. Compare 21 C.F.R. §80.1(i)(1) and (i)(4) as first promulgated at 38 F.R. 20739 (August 2, 1973) with 21 C.F.R. §105.85(1) and 105.85(j) as recodified at 42 F.R. 14333-14334 (March 15, 1977).

The agency's approach throughout most of the history of these regulations has been to provide for two partially repetitive lists of the ingredients on the label for dietary supplements. The first list mandated by the regulations is a listing of vitamin and minerals in tabular form and in a prescribed order giving percentages of the U.S. RDA's present in the product for each such vitamin or mineral ingredient. 21 C.F.R. §105.85(i). In addition, the regulations require "a separate list" of ingredients in accordance with the general ingredient labeling provisions of the Federal Food, Drug, and Cosmetic Act. 21 C.F.R. §105.85(j). In the second list, the agency requires the inclusion of all of the ingredients which make up a dietary supplement, including a repetitive listing of the vitamins and minerals previously listed in tabular form. This requirement for a second list represents a departure from earlier law where, under the agency's regulations, only a listing of the vitamins and minerals and a statement of their corresponding nutritional usefulness was required.

The difference between these two types of listings is very significant. The first listing of vitamins and minerals is prescribed by the agency in a specific fashion so as to show the usefulness of the food in terms of supplementing the diet with the various ingredients included in the dietary supplement. The second listing of ingredients does not distinguish between active and inactive ingredients and requires, in accordance with §403(i) [21 U.S.C. §343(i)], the ingredients to be listed in descending order of predominance by weight. Such listing, in terms of weight, does not take into account,

nor show, the relative nutritional significance of the ingredients of the products.

The purpose of requiring two lists of ingredients in different formats has never been completely clear in these regulatory proceedings. When the regulations were first promulgated on August 2, 1973, the provision for the separate list stressed that the list had to include the natural source or chemical form of the vitamins or minerals included in the dietary supplement.[39]

After the remand, the agency modified the separate listing provision. Instead of requiring merely a list of ingredients with the corresponding references to the natural source or chemical form of nutrients, the regulations in their final form now require that the list be one for "all ingredients used in the manufacture of the product." 21 C.F.R. §105.85(j) as recodified at 42 F.R. 14334 (March 15, 1977). This new, more expansive provision appears to be designed to cover inactive ingredients of the dietary supplement along with the active ingredients which are intended for use in supplementing the diet by increasing total dietary intake. The second listing which now is required to include all of the pharmacological ingredients of the product, is clearly inappropriate in and of itself for conveying any information to consumers as to the usefulness of any product ingredient for dietary supplementation. For example, if the largest single ingredient in a dietary supplement is a binder or other pharmacological component, it would have to be listed first on the list of separate ingredients ahead of the significant components which are intended for dietary supplementation. It is respectfully submitted that this confusing listing requirement is unsupportable on this record and should be invalidated as being contrary to the spirit of §403(j) of the Act. [21 U.S.C. §343(j)]. Any ingredient listing for these types of products inherently requires a breakdown geared towards rationally presenting the intended purpose and significance as to dietary supplementation. Ingredients should not be listed in a functionally hodge-podge manner which detracts from their "dietary" significance by emphasizing ingredient weight as a sole listing criteria.

In promulgating the final regulations, the agency took note of

39. "A separate list of ingredient in the product shall be included on the label pursuant to the requirements of Part 1 of this chapter. Such list shall include the natural source of a chemical of each individual nutrient present in the dietary supplement." 21 C.F.R. §80.1(i)(4), 38 F.R. 20739 col. 2 (August 2, 1973).

the potential for confusion in the second separate listing of "all" ingredients. See 41 F.R. 46167 (Oct. 19, 1976).[40]

Once again, however, the Commissioner in the final form of the regulations failed to take into account the new vitamin and mineral legislation and its implications for these labeling provisions. As already noted, the new vitamin and mineral legislation prohibits the agency from restricting combination of non-vitamin and mineral food ingredients, (such as rutin and bio-flavonoids) with vitamins and minerals in dietary supplements. Under the new statute, it is permissible to market such combinations as "dietary supplements." The statute expressly recognizes that such "other ingredients" are within the concept of foods for special "dietary" use by reason of their purpose in supplementing the diet by increasing the total dietary intake of these non-essential ingredients.[41] Yet, the agency, in promulgating the final regulations, completely failed to make provision for the manner of listing such non-vitamin and mineral ingredients of dietary supplements which ingredients are intended for the dietary purpose and which are generally not intended for a pharmacological effect, as are preservative, stabilizers, etc.

In its current form, the regulations leave no room for listing these ingredients, except as part of the confusing second "separate list" of all the ingredients which include the "weight" laden pharmacological components. Since the new statute requires that these non-vitamin and mineral food ingredients be listed on the label only as part of a list of all the ingredients of the product [§411(b)(2)(A)], the agency's continuation of the bifurcated system of listing of ingredients has the result of requiring that they be listed as part of an admittedly confusing list in a format which is unintelligible to the consumer. This result is clearly contrary to the statutory purpose of providing regulations which will ensure information sufficient to enable consumers to use these types of products. See §403(j) [21 U.S.C. §343(j)].

The confusing and deceptive result inherent in these regulations in their final form is expressly anticipated and prohibited by the new vitamin and mineral legislation:

> "The labeling for any food to which this section applies may not list its ingredients which are not vitamins or minerals (i) except as a part of a list of all

40. The Commissioner's statement failed to address or resolve the issue of confusion raised by the objection.

41. See §411(c)(3)(C) [21 U.S.C. §350(c)(3)(C)] and discussion under Point VI:A, *supra*.

> the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations under section 403 of this Act. *To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary."* (Emphasis added.) §411(b)(2)(A) [21 U.S.C. §350(b)(2)(A)]

The listing, as contemplated by current form of the regulations, would clearly result in unfair competition between products which contain vitamins and minerals alone and those which also contain certain other food ingredients, in accordance with differing philosophies of nutrition. The coherent and well-organized listing of vitamins and minerals as required by the agency's first list of ingredients, would be the same for both products, while the additional ingredients in the dietary supplement which included the other food ingredients would be relegated to the second all-encompassing, confusing "separate" list of ingredients. The consumer comparing two such products and directing his attention primarily to the first tabular listing of vitamins and minerals only, would be unable to distinguish the two products, thereby giving a manufacturer, who excluded non-vitamin and mineral food ingredients, an unfair competitive advantage in terms of price and composition of his product. Contrary to the express provisions of the statute, the agency apparently did not take into account what new labeling requirements would be necessary with respect to listing of ingredients as a result of the legislative sanction for the inclusion of non-vitamin and mineral food ingredients in dietary supplements.

It is respectfully submitted that the format for listing of ingredients, as currently promulgated by the agency, is, unsupported by substantial evidence, arbitrary, capricious, and not in accordance with law.

VIII.

THE AGENCY ERRED IN THE CONDUCT OF THE REMAND DIRECTED BY THIS COURT.

A. The Promulgated Standard of Identity Fails to Make Provision for Many Essential Nutrients.

The regulations in their final form continue to exclude from the

standard of identity (as it finally was promulgated with respect to pregnant and lactating women and children under the age of twelve years,) all substances whose essentiality for human nutrition has been established but for which no R.D.A. has as yet been established.[42] For example, Vitamin K is recognized as essential in human nutrition, by the agency's own admission [see 21 C.F.R. §105.3 (c) as recodified at 42 F.R. 14329, March 15, 1977]. Yet, the standard of identity, as finally promulgated by the agency [21 C.F.R. 105.85(d)(1)], fails to list Vitamin K even as an optional ingredient for dietary supplements.

It is hard to imagine a clearer directive than the one which was issued by this Court with respect to these substances. The agency was *ordered* to include as part of the standard of identity, at least as optional ingredients, all vitamins or minerals whose essentiality in human nutrition had been established even though no U.S. RDA had been determined. The only option given the agency was that of developing additional factual information upon the remand with respect to the precise manner of their incorporation in the standard of identity in terms of quantity or in terms of mandatory as opposed to optional ingredients. Instead, the agency chose to consciously disregard the order of this Court. See *NNFA v. FDA, supra,* 504 F.2d 786-787, text and accompanying notes.

No formal findings of fact with respect to this unilateral conclusion of the Commissioner were made. (40 F.R. 23246 Col. 2, May 28, 1975.) No citations of the record of these hearings were included as part of this decision to contravene the ruling of this Court. No factual basis was shown for excluding such nutrients as Vitamin K from the standard of identity, at least as optional ingredients.

The remand proceeding was not a license to disregard the rulings of this Court. Petitioners specifically advised the agency of its error in this respect and requested that the agency comply with this Court's ruling by incorporating all essential nutrients as at least optional ingredients in the standard of identity even though no U.S. RDA had been established. In response to the agency's unilateral position, petitioners advised the Commissioner that "the record at present is totally devoid of any evidence in this respect. Consequently, the record must be reopened and the hearings resumed for the purpose of determining the quantity of these

42. The FDA states that delays in establishing RDA's are due to budgetary considerations. 40 F.R. 23246, col. 1 (May 28, 1975).

essential ingredients which are appropriate for inclusion in dietary supplements."[43]

This Court has enjoined the enforcement of so much of the regulations as prohibited the inclusion of these essential nutrients as optional ingredients in dietary supplements. *NNFA v. FDA, supra,* 504 F.2d at 787. Since the agency failed to comply with the remand directions, it is respectfully submitted that such injunction be continued. The agency's failure to comply renders the current standard of identity unsupported by substantial evidence, arbitrary, capricious and not in accordance with law.

B. The Agency Failed to Comply with this Court's Direction as to the Criteria for Future Modification of the Standard of Identity.

One of the reasons for the remand proceedings was this Court's concern "with the all or nothing attitude" adopted by the FDA in promulgating the original standard of identity. *NNFA v. FDA, supra,* 504 F.2d at 783. This Court was specifically concerned with the fact that an "escape clause" in the regulations permitting future modifications of the standard of identity [§80.1(b)(4)] did not properly set forth the statutory criteria involved which would permit deviations from the standard of identity.

> " . . . Moreover, even apart from the important point that the escape clause relates only to combinations and not to the maxima, it is not sufficiently clear to us on the wording of §80.1(b)(4), and certainly not on the cryptic wording of paragraph 3 of the preamble, *that the agency intends to evaluate §80.1(b)(4) petitions in light of a balancing of freedoms infringed against the increased dangers of consumer confusion which would be triggered by allowance of each additional product — as we believe the reasonableness requirement of §401 requires it to do,* in a manner set forth in greater detail below. . . . " *NNFA v. FDA,* 504 F.2d at 784-785. (Emphasis added).

This Court laid down specific criteria with respect to which deviating formulations should be permitted. The Court directed that the "escape clause" provisions in the regulations "be modified to permit upward revisions in the maxima for the particular vitamins

43. Exceptions, Objections and Comments of NNFA and NAPM re Tentative Amendments of Final Orders, submitted July 14, 1975, pages 13, 14-15.

and minerals and that the criteria be broadened to conform to the standards of §401." *NNFA v. FDA, supra,* 504 F.2d at 785.

Once again, the agency has simply declined to comply with this Court's ruling. The final form of the regulations includes an escape clause which makes no reference to this Court's specific criteria and instead states only that any amendment to the standard of identity must "promote honest and fair dealing in the interest of consumers." 21 C.F.R. §105.885(a)(5) as recodified at 42 F.R. 14331, March 15, 1977. This provision would require that amendments to the standard of identity independently promote "honesty and fair dealing in the interest" of consumers. This Court, however, established further criteria which permit amendments and deviations from the standard of identity if upon balancing the factors deemed crucial by the Court, the proposed non-conforming products do not interfere with the statutory goal of promotion of honesty and fair dealing in the interest of consumers, even if they do not "promote" it per se.

Petitioners requested the agency to expressly incorporate the seven criteria established by this Court into the "escape clause" provision in the regulations.[44] The agency declined to incorporate

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44. "It is submitted that the following language should be included here incorporating the criteria established by the Court:

> 'Any such petition shall be submitted in the form set forth in §2.65 of this chapter. In ruling upon such applications, the commissioner among other factors shall consider:
>
> 1. The degree of increased potential consumer confusion if the application is granted.
>
> 2. The extent of consumer demand for the product.
>
> 3. The extent of expert scientific support for the product.
>
> 4. The possibility of reducing confusion by appropriate label statements.
>
> 5. Cost advantages or disadvantages to consumers as a result of the application.
>
> 6. The dependability of scientific information relied on by the Commissioner adverse to the application.
>
> 7. A balancing of the freedoms infringed against any increased danger of consumer confusion'"

Exceptions, Objections and Comments of NNFA and NAPM re Tentative Amendments of Final Orders, dated July 14, 1977, at p. 21.

this Court's criteria, and therefore violated the remand directions of this Court. Accordingly, the regulations as currently drafted are invalid as arbitrary, capricious and not in accordance with law.

C. The Final Regulations Improperly Restrict Representations Concerning the Availability of Iron in the Food Supply for the Purpose of Meeting the Requirements of Children and Women of Child-Bearing Age.

The agency's final form of 21 C.F.R. §105.60(b)(2)[45] is in violation of this Court's ruling with respect to the availability in the food supply of iron needed to meet the requirements of children and women of child-bearing age.

This Court upheld the general prohibition against representing that "a balanced diet" could not supply sufficient nutrients for the American population, but noted:

> "Nevertheless we are obliged to fault §125.2(b)(2) with respect to iron, for there was strong and uncontradicted evidence that it was very difficult for women of child-bearing age and for children to obtain an adequate supply of this even from a balanced diet. On the remand we have directed, the FDA may either adduce further evidence on this point, or, as might be preferable, insert a proper qualification in §125.2(b)(2)." (Footnote omitted.) *NNFA v. FDA, supra,* 504 F.2d at 802.

The ruling of this Court was based on the evidence in the record which clearly showed the difficulties with respect to supplying sufficient iron for these sensitive groups. The Court in passing also noted that even the FDA had made a finding that it was "impractical" to meet the iron needs of adult women with conventional foods. *Id.* n. 75. The basic ruling of the Court, however, was that even a "balanced diet" was insufficient to meet the specific needs of these groups for this nutrient.

The agency upon remand inserted a qualification in this prohibition permitting only a reference to the fact that it might be "impractical" to meet the iron needs of these groups from a diet of conventional foods.[46] The new proviso, was never prohibited by the

45. As recodified at 42 F.R. 14329, March 15, 1977, formerly 21 C.F.R. §125.2(b)(2) quoted at 504 F.2d 799, note 68.

46. See 21 C.F.R. §105.60(b)(2), as recodified at 42 F.R. 14329 (March 15, 1977).

original C.F.R. §125.2(b)(2)! The framing of a proviso in terms of "impracticality" has the effect of suggesting that the prohibitory portion of this section includes statements indicating that it may as a general matter be "impractical" for other groups to meet their dietary needs from conventional foods. There is no support in the record for such a prohibition. By improperly wording the proviso, the agency has improperly expanded the scope of the prohibition without any supportive substantial evidence of the record.

This Court upheld this regulatory provision only on a narrow reading, limiting it to a prohibited representation as to persons who in fact *do* eat a balanced diet. Nothing in this Court's decision suggested that the agency could prohibit truthful statements that it might be "impractical" for some people to eat a balanced diet, therefore necessitating or warranting dietary supplementation. The "practicality" or "impracticality" of eating a balanced diet for diverse ethnic, cultural and economic groups and individuals within the United States was not at issue before the agency, and the final regulations improperly imply a prohibition upon statements or representations in this regard.

Petitioners specifically called the foregoing to the attention of the agency,[47] but the agency declined to modify the regulations.[48] Section 105.60(b)(2) should therefore be invalidated as being inconsistent with the ruling of this Court, unsupported by substantial evidence, and arbitrary, capricious and not in accordance with law.

D. The Agency Erred in Refusing to Modify §105.60(b)(2) As Regards Vitamin B-6 (Pyridoxine), Folic Acid and Magnesium.

In discussing the adequacy of the food supply for supplying various nutrients, this Court noted that certain petitioners, upon the prior appeal, had questioned the sufficiency of the food supply with respect to Vitamins B-6 and folic acid as well as the mineral magnesium. The Court, however, was unable to rule on those issues because relevant pages of the transcript had inadvertently not been supplied to the Court. See *NNFA v. FDA, supra,* 504 F.2d 801-802, note 73.

Upon the remand the instant petitioners called to the attention

47. Exceptions, Objections and Comments of NNFA and NAPM re Tentative Amendment of Final Orders, dated July 14, 1975, at pages 18-19.

48. The Commissioner gave no explanation for insisting on the improperly worded proviso. See 41 F.R. 46169, col. 1, ¶ 20, October 19, 1976.

of the Commissioner, transcript references showing uncontradicted evidence that the food supply is in fact inadequate with respect to levels of these three nutrients.[49]. The agency was asked in the interest of factual accuracy to expand the qualification of §125.2(b)(2), [now §105.60(b)(2)] to include these substances with respect to which the transcript references had been inadvertently not supplied to the Court. In the alternative a hearing before the agency was requested for this purpose.

The agency's response to this request was once again in the negative.[50] The attention of the Court is therefore once again respectfully directed to the record citations which show the lack of sufficient quantitites of these nutrients in the food supply.[51]

At the least, this was an issue with respect to which the Commissioner should have either dealt expressly, or granted a hearing, pursuant to the requirements of §701(e) of the Federal, Food, Drug and Cosmetic Act, [21 U.S.C. §371(e)]. The failure of the Commissioner to act on this uncontradicted evidence renders the prohibition, as it applies to these three nutrients, unsupported by substantial evidence, and arbitrary, capricious and not in accordance with law.

E. The Regulations Improperly Prohibit Representations That There May Be a Difference Between Natural and Synthetic Vitamins.

Since the ruling of this Court, additional information has been placed in the record which demonstrates that the agency is aware of a significant difference between natural and synthetic vitamins, at least with respect to Vitamin K. In the Federal Register, May 28, 1975, the Commissioner stated:

> ". . . the Commissioner does not believe that current scientific knowledge warrants any potency restrictions in the interest of safety upon use of the

49. Exceptions, Objections and Comments of NNFA and NAPM re Tentative Amendments of Final Orders, dated July 14, 1975 at pp. 19-20.

50. See 41 F.R. 46169, col. 1, ¶ 22, where the Commissioner simply ignores the transcript references supplied by petitioners and states that he is not aware of any evidence to indicate a deficiency in the food supply for these nutrients.

51. WD-46 Briggs, p. 18, WD-46 Olson, p. 10, TR. 28575, White, WD-46, White, p. 8. Copies of these references will be furnished to the Court as part of the deferred Appendix to be filed herein.

> vitamins (mandatory or optional) listed in §80.1(f)(1) or upon the use of choline. However, with regard to vitamin K, the Commissioner is presently of the opinion that synthesized vitamin K (menadione) could only be intended for therapeutic use, and, because of the potential for harm involved in its use, that it should be dispensed only on prescription. *The naturally occurring vitamin K (phylloquinone), on the other hand, appears to be generally recognized as safe for use as a dietary supplement at least up to levels providing 100 mcg per recommended daily quantity."*(Emphasis added.) 40 F.R., p. 23248, May 28, 1975.

Clearly there is a significant "difference" between the natural form of Vitamin K and the synthetic form in terms of toxicity. Surely in light of this information, the agency cannot support a prohibition on any representations concerning this "difference" or as to the superiority of the natural form of Vitamin K over the synthetic form with safety conditions in mind.[52] It is respectfully submitted that the agency should be directed to insert a qualifying provision in §105.60(b)(6), exempting Vitamin K from the prohibitions.

IX.

THE AGENCY IMPROPERLY INCORPORATED FOOD ADDITIVE RESTRICTIONS ON VITAMINS AND MINERALS AS PART OF THE DIETARY SUPPLEMENT REGULATIONS.

Petitioners respectfully submit that the agency has seriously erred in incorporating into these proceedings attempted restrictions on vitamins and minerals on account of an alleged possibility or potential for "food additive" status under the Federal Food, Drug and Cosmetic Act.

On May 28, 1975, in response to the decision of this Court, the agency for the first time in the history of these dietary supplement proceedings proposed to "cross reference" in these regulations various alleged restrictions on the composition of dietary supplements which would be applicable by virtue of provisions of the Federal Food, Drug and Cosmetic Act not directly involved in this proceeding. Included among these were cross-references to

52. See also discussion at p. 33, *supra*, relative to constitutional First Amendment rights as to commercial speech.

regulations such as those governing the sales of Vitamins A and D (21 C.F.R. §250.109-.110) and also a complex and controversial provision concerning the potential food additive status of vitamins or minerals included in dietary supplements.[53] Petitioners filed exceptions to this approach,[54] but the agency retained these "cross reference" restrictions in the final form of the regulations.[55]

The issues as to food additive status for any substance are complex, factual questions under the Federal Food, Drug and Cosmetic Act, which should never have been injected into these proceedings. Certainly, there is nothing in the decision of this Court which permitted the agency upon the remand to add additional restrictive provisions to the regulations. At best, these cross-references are unnecessary. The regulations contain a separate express provision pointing out that these regulations are not intended to exempt dietary supplements from compliance with any other applicable law or regulation.[56]

In fact, the inclusion of these "informational" provisions is seriously prejudicial to petitioners in that without any opportunity for a factual hearing the regulations conclude that any vitamins or minerals could be considered food additives under the statute in vaguely defined circumstances. This very issue is currently pending before various district courts where an opportunity for a full factual presentation is available. The inclusion of such a provision in these regulations would improperly serve to preempt the appropriate forum for resolving the factual and legal issues concerning the potential food additive status of any substance.

Basically, the statute provides specific distinctions between "foods" and "food additives." "Foods" are governed by

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53. See 40 F.R. 23247-23248, 23249-23250, May 28, 1975.

54. See Exceptions, Objections and Comments of NNFA and NAPM re Tentative Amendments of Final Orders dated July 14, 1975, pp. 23-25.

55. 21 C.F.R. §105.85(f)(1)-(8), as recodified at 42 F.R.14332-14333, March 15, 1977.

56. See §105.85(a)(4):

> "*Other requirements of law:* Compliance with the requirements of this section, does not exempt a dietary supplement from other requirements of any other applicable regulations whether or not cross-referenced herein." (as recodified at 42 F.R. 14331, March 15, 1977).

the provisions of §402(a) [21 U.S.C. §342(a)] of the statute which protect the public in terms of rendering foods subject to sanction if they are adulterated, and in fact injurious to the public health. See §402(a)(1), U.S.C. §342(a)(1). On the other hand, if a substance is a food additive under the statute, it is subject to sanction even if there is no known hazard to health involved with the use of the product. Instead, under the statutory definition, §201(s), [21 U.S.C. §321(s)] and its related substantive provisions, §409 (21 U.S.C. §349), these substances may not be used "in the absence of affirmative proof that they are generally recognized as safe." This is a complex and burdensome standard, akin to that imposed under the statute as a criteria for approval of new drugs. See, *e.g.*, §201(p) 21 U.S.C. §321(p).[57]

The purpose of the agency's eleventh-hour inclusion of food additive provisions in these regulations without any factual record support, is evident. This Court and the Congress invalidated the agency's prior attempted "drug classification for vitamins and minerals. *NNFA v. FDA, supra,* 504 F.2d at 788-789; §411(a)(1)(B) [21 U.S.C. §350(a)(1)(B)]. Having failed to restrict non-conforming dietary supplements as "drugs, the agency now seeks to bypass the above by establishing the option of regulating these products as "food additives."

The attempted food additive provisions are also invalid on their face in that they do not conform to the statutory definition. The statute, in §201(s) [21 U.S.C. 321(s)] sets forth standards as to what constitutes "general recognition of safety" depending on the time frame involved. In the case of "food additives" in use prior to 1958, the statute permits general recognition of safety based on common use of the ingredient in food. In direct contravention of the statutory definition, the instant regulation fails to include such a provision. This is highly significant with respect to vitamins and minerals in light of their long-time use for many years prior to 1958. For this reason alone, the "food additive cross reference" of §105.85(f)(8) should be invalidated. See *NNFA v. FDA, supra,* 504 F.2d at 789, note 35.

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57. The classifying of vitamin and mineral as potential food additives could also subject them to the harsh sanctions of the Delaney clause in §409 of the Act (21 U.S.C. §49) which, as is currently being suggested for Saccharin, would require a total ban on the use of the substance in the event that animal tests showed any malignancy, irrespective of the dosages used. If this were applied to vitamins and minerals, it could lead banning of all supplementation for an essential nutrient! The applicability of food additive provision is thus particularly subject to question in the case of "foods for special dietary use."

Finally, the agency itself has recognized the impropriety of adding new restrictions in these regulations which were not mandated by this Court as part of the directed remand proceedings. The May 28, 1975 announcement in the Federal Register had originally proposed some additional provisions, and after objection, the agency noted "that although the Commissioner believes that §125.3(c) was a desirable provision, he has concluded that it was not within the scope of the remand instructions of the Court of Appeals, and accordingly the provision has been deleted from the regulations issued below." 41 F.R. 46169, Col. 1 ¶21, (October 19, 1976). Similarly, the food additive provisions were not part of the remand instructions of this Court and it is respectfully submitted that this Court should direct that these improper provisions be deleted.

X.

THE REGULATORY PROVISIONS CONCERNING EXPIRATION DATING FOR DIETARY SUPPLEMENTS ARE INVALID.

The regulations in their final form include a provision requiring the labels of dietary supplements to contain an expiration date statement. As of the date to be specified on the label, the regulations require that the dietary supplement "contain *not less than* the quantity of each such vitamin and/or mineral, as set forth on its label", 21 C.F.R. §105.85(l), as recodified, 42 F.R. 14334, (March 15, 1977). (Emphasis added.)

It is respectfully submitted that this absolute requirement that the product contain "not less than" the label amount is inconsistent with the standardized practice in the manufacture of vitamin and mineral products. The standard reference used to measure potency of vitamin and mineral products in the U.S. Pharmacopoeia, which includes quantitative ranges within which vitamin drug products must fall in terms of the required strength. In the case of all vitamins and minerals, the U.S.P. allows a range for tolerances, including percentages less than 100 percent of label value in accordance with commercial manufacturing practices. There is absolutely, no factual justification in the record of these proceedings which would permit the agency to place more stringent potency requirements on dietary supplements than are commonly required for drug products, where exact potency is much more crucial than here.

It is respectfully submitted that the absolute and inflexible

potency limitation, as expressed in the expiration date provision of these regulations is unsupported by substantial evidence, arbitrary, capricious and not in accordance with law.

CONCLUSION

It has been shown that in promulgating these final regulations, the agency completely failed to comply with statutory, administrative due process requirements. In attempting to modify the regulations in light of the new vitamin and mineral legislation, the agency seriously misunderstood the significance of the changes which it sought to implement and the full scope of the various further changes which are necessary and appropriate in light of the complex interrelationships among the various regulatory provisions. In implementing the remand, the agency deliberately disregarded many of the express directions of this Court without good cause and sometimes without attempting any explanation.

It is respectfully submitted that the course of administrative proceedings had herein since the prior decision of this Court, and the agency's specific actions in hastily promulgating these final regulations have placed an unfair burden upon this Court and the parties. The approach taken by the agency has been contrary to the public interest in resolving the issues raised by the dietary supplement regulations.

The result is that the regulations in their current form are unsupported by substantial evidence and are arbitrary, capricious and not in accordance with law. Petitioners respectfully submit that these regulations should be vacated.

Respectfully submitted,

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ADDENDUM

ADMINISTRATIVE PROCEDURE ACT

15 U.S.C. §553. Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

FEDERAL FOOD DRUG AND COSMETIC ACT

§201 [21 U.S.C. §321]. Definitions; generally

For the purposes of this chapter—

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

(s) The term "food additive means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use. . . .

§402 [21 U.S.C. §342. Adulterated food

A food shall be deemed to be adulterated—

Poisonous, insanitary, etc., ingredients

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health;

§403 [21 U.S.C. §343. Misbranded food

A food shall be deemed to be misbranded—

False or misleading label

(a) If its labeling is false or misleading in any particular.

Label where no representation as to definition and standard of identity

(i) If it is not subject to the provisions of subsection (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without

naming each: *Provided*, That, to the extent that compliance with the requirements of clause (2) of this subsection is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

Representation for special dietary use

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

§411 [21 U.S.C. §350. Vitamins and minerals — Authority and limitations of Secretary; applicability

(a)(1) Except as provided in paragraph (2)—

(A) the Secretary may not establish, under section 321n, 341, or 343 of this title, maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;

(B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful;

(C) the Secretary may not limit, under section 321(n), 341, or 343 of this title, the combination or number of any synthetic or natural—

(i) vitamin,
(ii) mineral, or
(iii) other ingredient of food,

within a food to which this section applies.

(2) Paragraph (1) shall not apply in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this subparagraph, the term "children" means individuals who are under the age of twelve years.

Labeling and advertising requirements for foods

(b)(1) A food to which this section applies shall not be deemed under section 343 of this title to be misbranded solely because its label bears, in accordance with section 343(i)(2) of this title, all the ingredients in the food or its advertising contains references to ingredients in the food which are not vitamins or minerals.

(2)(A) The labeling for any food to which this section applies may not list its ingredients which are not vitamins or minerals (i) except as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations under section 343 of this title. To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations

promulgated by the Secretary.

(B) Notwithstanding the provisions of subparagraph (A), the labeling and advertising for any food to which this section applies may not give prominence to or emphasize ingredients which are not—

(i) vitamins,

(ii) minerals, or

(iii) represented as a source of vitamins or minerals.

Definitions

(c)(1) For purposes of this section, the term "food to which this section applies" means a food for humans which is a food for special dietary use—

(A) which is or contains any natural or synthetic vitamin or mineral, and

(B) which—

(i) is intended for ingestion in tablet, capsule, or liquid form, or

(ii) if not intended for ingestion in such a form, does not simulate and is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

(2) For purposes of paragraph (1)(B)(i), a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

(3) For purposes of paragraph (1) and of section 343(j) of this title insofar as that section is applicable to food to which this section applies, the term "special dietary use" as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

(A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

(B) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

(C) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

§ 701 [21 U.S.C. §371. Regulations and hearings — Authority to promulgate regulations

(a) The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

Procedure for establishment

(e) (1) Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352(d) or (h), of this title shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is

based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

Review of order

(f) (1) In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of Title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 346 and 347 of Title 28.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

CERTIFICATE OF SERVICE

Re: 77-4097
National Nutritional Foods Assoc. v.
Kennedy

STATE OF NEW JERSEY :
: ss.:
COUNTY OF MIDDLESEX :

I, Muriel Mayer, being duly sworn according to law, and being over the age of 21 upon my oath depose and say that: I am retained by the attorney for the above named Petitioners.

That on the 2nd day of August , 1977, I served the within

Brief for Petitioners

in the matter of National Nutritional Foods Assoc., The National Assoc. of Pharmaceutical Mfgs & Solgar Co., Inc.
upon Charles R. McConachie, Esq., United States Department of Justice
Antitrust Division, Consumer Affairs Section, Washington, D.C.
20530

by depositing two (2) true copies of the same securely enclosed in a post-paid wrapper, in an official depository maintained by the United States Government.

Muriel Mayer
Muriel Mayer

Sworn to and subscribed
before me this 2nd day
of August 1977.

Lorraine Leotta
A Notary Public of the
State of New Jersey.
LORRAINE LEOTTA
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires April 13, 1982